

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY


(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 10 FEB 2006

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Applicant's or agent's file reference P14522PCDK	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/DK2004/000759	International filing date (day/month/year) 03.11.2004	Priority date (day/month/year) 03.11.2003	
International Patent Classification (IPC) or national classification and IPC A61K7/06			
Applicant CORTEX TECHNOLOGY APS et al			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 2 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 02.09.2005		Date of completion of this report 09.02.2006	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer Drew, C Telephone No. +49 89 2399-8494	



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/DK2004/000759

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-14 as published

Claims, Numbers

1-11 received on 21.01.2006 with letter of 19.01.2006

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/DK2004/000759

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1 to 11
	No: Claims	
Inventive step (IS)	Yes: Claims	1 to 11
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1 to 11
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

PCT/DK2004/000759

- 1 The following documents (D) from the international search report will be referred to:

D1 WO 01 85182 A2

D2 DATABASE WPI Week 200369, Derwent Publications Ltd., London, GB;
Class A89, AN 2003-728134, XP002985214 & KR 2003 025 895 A

Section I

- 2 support for the introduction of the word "Pharmaceutical" at the end of claim 1 can be found at page 8, lines 10 to 14 of the published application. Claim 10 is a combination of claims 10 and 12 of the published application. Dependent claims 2 to 9 and 11 correspond to claims 2 to 9 and 13 of the published application.

Section V

- 3 *Novelty (Article 33(2) PCT)*

None of the documents from the international search report would appear to disclose compositions comprising a deep sea fish extract and a rooibos extract, so that claims 1 to 11 would therefore appear to be novel.

- 4 *Inventive Step (Article 33(3) PCT)*

- 4.1 D1 relates to a composition for oral administration comprising a fish cartilage extract and a plant extract comprising a hydrophilic antioxidant, *e.g.* grape seed extract, and a hydrophobic antioxidant, *e.g.* tomato extract. The composition is used for reducing signs of aging of the skin.
- 4.2 D2 teaches the use of rooibos extract for the treatment of skin aging.
- 4.3 However, there is no suggestion that the present compositions might find use in the cosmetic treatment of hair loss.

4.4 Present claims 1 to 11 would therefore appear to exhibit an inventive step.

Section VII

5 The opening paragraphs of the description do not contain any reference to D2, contrary to Rule 5.1(a)(ii) PCT.

Section VIII

The description has not been adapted to the new claims, clarity (Article 6 PCT).

New claims filed in response
to the Written Opinion of 19/12-05

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CLAIMS

1. A composition comprising the components:

- 5
- an extract of a deep sea fish; and
 - an extract of rooibos (*aspalathus linearis*); and
 - optionally an extract of bearberry (*arctostaphylos uva-ursi*);

as active components thereof; and

- 10
- optionally one or more fillers or ancillary agents conventionally used in the formulation of pharmaceutical compositions.

2. A composition according to claim 1, wherein the active component bearberry
15 (*arctostaphylos uva-ursi*) is omitted.

3. A composition according to claim 1 comprising:
- an extract of deep sea fish;
 - an extract of rooibos (*aspalathus linearis*); and
 - 20 - an extract of bearberry (*arctostaphylos uva-ursi*).

4. A composition according to any of the claims 1 - 3 further comprising one or two components selected from the group comprising a horsetail extract (*equisetum arvense* L.) and a shellfish extract.

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5. A composition according to any of the claims 1 - 4 further comprising diacetyl boldine.

6. A composition according to any of the preceding claims, wherein the composition
30 is in a form suitable for oral administration, such as a tablet, a capsule, a lozenge or a sachet.

New claims filed in response 2
to the Written Opinion of 19/12-05

7. A composition according to any of the claims 1 – 5, wherein the composition is in a form suitable for topical administration to the scalp, such as a lotion, a cream, an emulsion, a foundation, a shampoo, a rinse, a hair liquid, a set lotion or a hair tonic.

5 8. A composition according to claim 2 or 3 in the form of a tablet intended for daily dosage, especially for cosmetic treatment of the skin and further comprising suitable ancillary agents and fillers as well as coating agents.

10 9. A method for the preparation of a composition according to any of the preceding claims, wherein the active components are mixed and via the conventional fillers or ancillary agents, if present, are formulated into the form suitable for the administration desired.

15 10. A method for the cosmetic treatment of hair loss by administering an effective amount of a composition according to any of the claims 1 – 8 to a subject in need thereof.

11. A composition according to any of the claims 1 – 8 for use as a medicament.

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